IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 14-1227-SLR/SRF
	)	
WATSON LABORATORIES, INC.,	)	
	)	
Defendant.	)	

PURDUE PHARMA L.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 14-1410-SLR/SRF
	)	
WATSON LABORATORIES, INC.,	)	
	)	
Defendant.	)	

PURDUE PHARMA, L.P.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 15-192-SLR/SRF
	)	
ACTAVIS LABORATORIES UT, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 4th day of March, 2016, having heard argument on, and

having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent Nos. RE41,408 ("the '408 patent") and RE41,571 ("the '571 patent") shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. **"Substantially first order plasma level increase:"**[1] "Plasma concentrations which increase over a specified period of time, and which are distinguished from immediate sharp increases." According to the background of the invention,

> experts are of the opinion that the form of administration of a medicinal drug contributes to the risk of addiction, and higher than necessary blood levels created immediately after administration of a drug such as buprenorphine, followed by a drastic decrease (causing in succession euphoria and then ineffective pain treatment), cause the patient to start to long for the next dosage (referred to as an 'iatrogenic' addiction).

('408 patent, col. 2:22-29; *see also* col. 23:49-55)[2] The advantage of the inventive method of administering pain relief to patients is that it "allows for reduced plasma concentrations of buprenorphine over a prolonged time period than possible according to prior art methods, while still providing effective pain management." (Col. 3:9-12) This is accomplished by a "first order rate of increase of blood plasma concentrations of buprenorphine" over a first specified period of time, "followed by a prolonged time period of [a second specified period of time] during which the plasma concentrations of

---

[1]Relevant to dependent claims 11, 21, and 23 of the '408 patent, as well as claims 1, 22, 24, 34, 37, 40, 48, 52, 53, 55 and 56 of the '571 patent.

[2]All references are to the specification of the '408 patent, which is substantially identical to the specification of the '571 patent.

buprenorphine are maintained according to substantially zero order pharmacokinetics" (Col. 3:38-41); that is, despite the expected "drop-off in the release rate of buprenorphine after the first 72 hours, [the inventive delivery system] nevertheless provide[s] a relatively small but sufficient release of buprenorphine to maintain analgesia and desirable plasma concentrations in the patients over a further period of time. . . ."[3] (Col. 4:61-65) The parties agree that the intent of the inventive methods are to deliver buprenorphine to a patient so as to avoid dramatic, immediate increases (or decreases) in the plasma concentrations of said opioid, as would accompany drug delivery systems such as injections.

2. Plaintiff has suggested using the word "steadily" to describe the "first order" plasma level increase, as that word was used in the specification. (Col. 25:64-26:4) Defendants argue that, because "there are periods of slower and faster [absorption - t]here are peaks and troughs" (Civ. No. 14-1227, D.I. 106 at 19), such an adverb would add ambiguity to the construction: "How significant those are, how substantial those are, and whether or not those will give you a steadily increasing plasma level such that it would be a first order plasma level." (*Id.*) Defendants also argue that the patentee was its own lexicographer, in that the term "'first order' pharmacokinetics" was defined in the patent "as plasma concentrations which increase over a specified time period." (Col. 6:20-22) As noted at oral argument, however, all of the claims at issue include a

[3]"The term 'zero ordering' pharmacokinetics contemplates an amount of drug released from a buprenorphine formulation which substantially maintains plasma concentrations at a relatively constant level." (Col. 6:50-53)

specified period of time;[4] therefore, such a definition does not give any meaning to the phrase "first order."

3. In sum, although the parties apparently do not dispute what a "first order plasma level increase" is, they cannot agree on how to describe it. The court has included the word "substantially" from all of the asserted independent claims, as that word indicates to one of skill in the art that the rate of increase need not be even;[5] rather, the plasma level simply must increase over a specified period of time and not be characterized by immediate, sharp increases. This construction accurately describes an agreed-upon phenomenon, and is consistent with the intrinsic and extrinsic evidence.[6]

4. The court has provided a construction in quotes for the claim limitation at issue. The parties are expected to present the claim construction consistently with any explanation or clarification herein provided by the court, even if such language is not included within the quotes.

United States District Judge

[4]"For all claims at issue here, the 'specified time period' refers to a period from 0 to 72 hours after administration of buprenorphine." (Civ. No. 14-1227, D.I. 56 at 7 n.4)

[5]*See as well* col. 6:50-53, where "zero ordering" pharmacokinetics is defined using adverbs such as "**substantially** maintains plasma concentrations at a **relatively** constant level." (Emphasis added)

[6]*See, e.g.,* Civ. No. 14-1227, D.I. 57 at 7 and D.I. 68 at 2. *See also*, Civ. No. 15-192, D.I. 43 at 4-9.